

# इंटरनेट

# मानक

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IS 6779 (1989): Thoracic Surgery Instruments - Forceps, Dissecting and Ligature, Mixer's Pattern [MHD 6: Thoracic and Cardiovascular Surgery Instruments]



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“Knowledge is such a treasure which cannot be stolen”



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*Indian Standard*

**THORACIC SURGERY INSTRUMENTS —  
FORCEPS, DISSECTING AND LIGATURE,  
MIXTER'S PATTERN — SPECIFICATION**

*( First Revision )*

भारतीय मानक

छाती सम्बन्धी शल्यक्रिया उपकरण — चिमटियां, विच्छेदक और बंध, मिक्सटर  
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NEW DELHI 110002

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**Price Group 2**

## FOREWORD

This Indian Standard (First Revision) was adopted by the Bureau of Indian Standards on 19 May 1989, after the draft finalized by the Thoracic and Cardiovascular Surgery Instruments Sectional Committee had been approved by the Medical Equipment and Hospital Planning Division Council.

This standard was first issued in 1972. In this revision, tolerances on various dimensions have been specified, an additional test for flexibility has been incorporated and the clauses on surface condition, marking and packing have been modified. Besides, a recommended sampling plan has been added.

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS 2 : 1960 'Rules for rounding off numerical values (*revised*)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

## Indian Standard

# THORACIC SURGERY INSTRUMENTS — FORCEPS, DISSECTING AND LIGATURE, MIXTER'S PATTERN — SPECIFICATION

( First Revision )

### 1 SCOPE

This standard prescribes requirements and tests for Mixer's pattern, dissecting and ligature forceps used in thoracic surgery.

### 2 REFERENCES

Indian Standards listed below are necessary adjuncts to this standard:

IS No.	Title
1501 (Part 1) : 1984	Method for Vickers hardness test for metallic materials: Part 1 HV 5 to HV 100 ( <i>second revision</i> )
3642 : 1978	General requirements for surgical instruments ( <i>first revision</i> )
4905 : 1968	Methods for random sampling
6528 : 1972	Specification for stainless steel wire
6603 : 1972	Specification for stainless steel bars and flats
7531 : 1975	Method for boiling and autoclaving test for corrosion resistance of stainless steel surgical instruments

### 3 MATERIAL

The instrument shall be made of stainless steel conforming to Designation 20Cr13 or 30Cr13 of IS 6603 : 1972.

### 4 SHAPE AND DIMENSIONS

**4.1** The shape and dimensions of the instrument shall be as shown in Fig. 1.

#### 4.2 Tolerances

Tolerances on linear dimensions shall be as given below:

$\pm 0.05$  mm on dimensions up to 2.0 mm

$\pm 0.1$  mm on dimensions above 2.0 mm and up to 5.0 mm

$\pm 0.2$  mm on dimensions above 5.0 mm and up to 20.0 mm

$\pm 0.5$  mm on dimensions above 20.0 mm and up to 50.0 mm

$\pm 1.0$  mm on dimensions above 50.0 mm and up to 100.0 mm

$\pm 2.0$  mm on dimensions above 100.0 mm

**4.2.1** The two halves of the instrument shall, however, not differ at any dimension and shall match with each other perfectly.

### 5 MASS

The mass of the instrument shall be  $50 \pm 5$  g.

### 6 HEAT TREATMENT

**6.1** The instruments shall be uniformly hardened and tempered to a hardness of 400 HV to 460 HV, when tested in accordance with IS 1501 (Part 1) : 1984.

**6.2** Mating surfaces on the same instrument, such as opposite jaws and shanks, shall not vary in hardness by more than 40 HV.

### 7 WORKMANSHIP

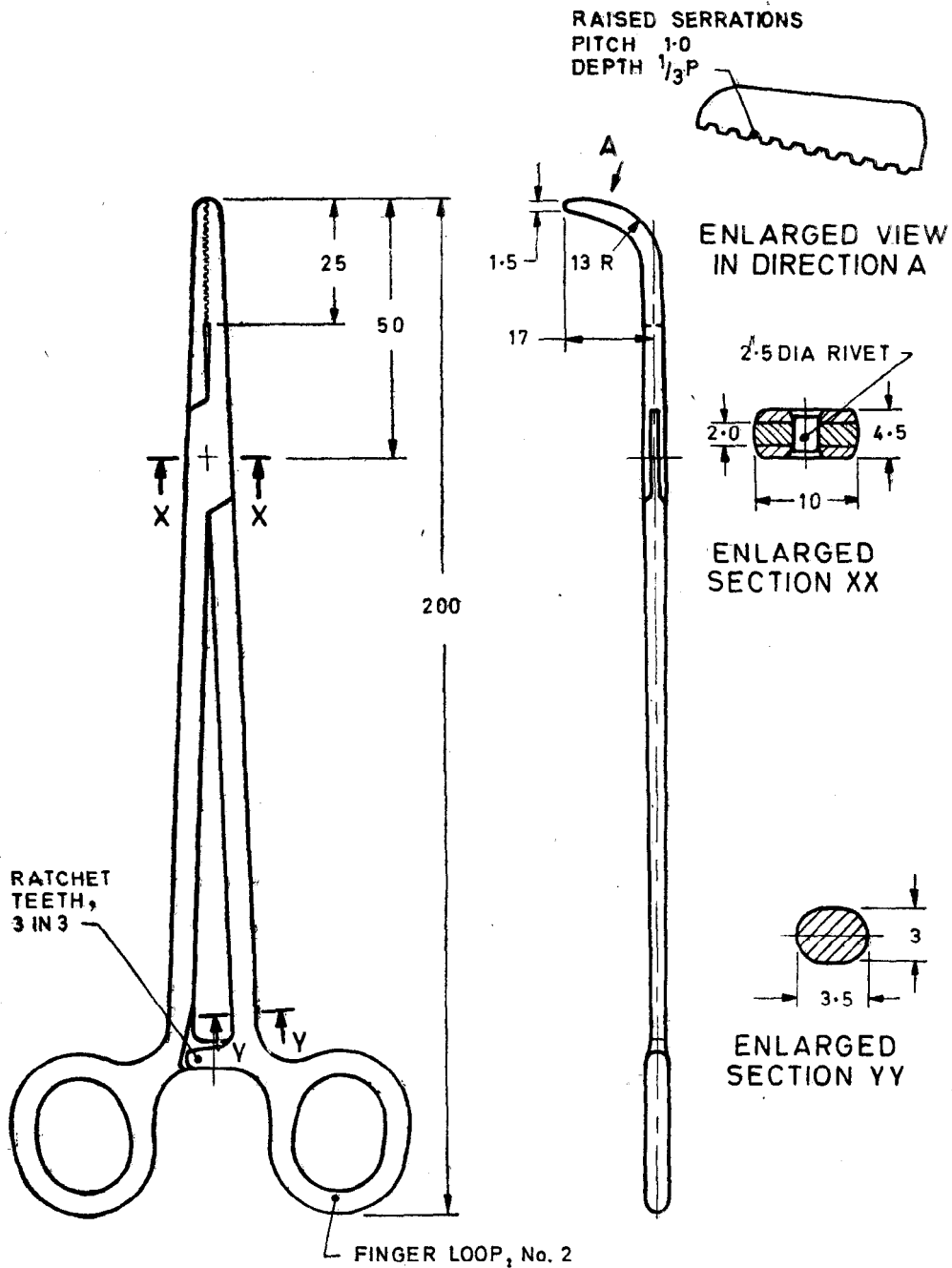
**7.1** The forceps shall be symmetrical and balanced, and the opening and closing movement shall be in one plane, smooth and jerk free.

**7.2** The joint shall conform to the relevant requirements of 6 of IS 3642 : 1978.

**7.3** The serrations on the jaws shall be transverse and truncated, and shall conform to the relevant requirements of Section 1 of IS 3642 : 1978.

**7.4** The ratchet teeth shall conform to Section 3 of IS 3642 : 1978. The forceps shall be symmetrical at each ratchet engagement.

**7.5** The finger loops shall be in accordance with the relevant requirements of Section 5 of IS 3642 : 1978.



All dimensions in millimetres.

FIG. 1 FORCEPS, DISSECTING AND LIGATURE, MIXTER'S PATTERN

## 8 SURFACE CONDITION

### 8.1 General

All surfaces shall be free from sharp edges, pores, crevices and grinding marks. The instruments shall be supplied free from residual scale, acid, grease, grinding and polishing materials. Compliance with these requirements shall be checked by visual inspection.

### 8.2 Surface Finish

The surface finish of the instrument shall be reflection-reducing, for example, satin finish, matt black finish.

NOTE — The satin finish should be effected by an appropriate procedure, such as grinding, brushing electropolishing and, in addition, satin finishing (glass beading or satin brushing). The finish should be uniform and smooth and it should reduce glare.

### 8.3 Passivation and Final Treatment

The instruments shall be treated by a suitable passivation process, for example, by electro-polishing or by treatment with 10 percent (v/v) nitric acid solution for not less than 30 minutes, at a temperature not less than 10°C and not exceeding 60°C. The instruments shall then be rinsed in water and dried in hot air.

NOTE — If the joint is lubricated, the lubricant should be non-corrosive and suitable for medical application according to the Indian Pharmacopoeia.

## 9 TESTS

### 9.1 Load Closure Test

By fixing one finger loop of the forceps in a vice, load shall be applied at the free finger loop by means of a pan or spring balance. The load at which the first ratchet just engages shall be noted. The load required to close the forceps on the first step of the ratchet shall be 13 to 20 N (1.3 to 2.0 kgf approximately).

### 9.2 Flexibility Test

**9.2.1** Each arm of the forceps shall be fixed in a vice so that the entire arm projects above the vice. By gradual application of force on the finger loop, the arm shall be deflected by 15 mm in the same plane as that of the finger loop. The arm shall not take a permanent set or break.

**9.2.2** Place a stainless steel wire of 5 mm dia, conforming to Designation 04Cr18Ni10 of IS : 6528 : 1972 between the tips of the instrument jaws. Fully close the instrument to the last ratchet position. Leave the instrument in this position for 3 h at room temperature.

After the test, no distortion, cracks or any other permanent modification in the instrument shall be visible.

### 9.3 Corrosion Resistance Test

The instruments shall be tested in accordance with IS 7531 : 1975. They shall show no sign of corrosion after the test.

## 10 MARKING AND PACKING

**10.1** The instruments shall be legibly and indelibly marked with the indication of the source of manufacture; the words 'stainless steel' or letters 'ss'; and the country of manufacture.

**10.2** Each instrument shall be wrapped in a suitable cushioning material like folded tissue paper. It shall then be put in a polyethylene bag or wrapped in wax paper. The instruments shall thereafter be packed in cartons in accordance with the current trade practice.

**10.2.1** Alternatively, the instruments may be packed as agreed to between the purchaser and the supplier.

**10.3** The packages shall be marked with the name of the instrument; indication of the source of manufacture; the words 'stainless steel'; and the country of manufacture.

## 11 SAMPLING

The scale of sampling and criteria for conformity of the instruments to the requirements of this specification shall be as agreed to between the purchaser and the supplier. A recommended sampling plan is given in Annex A.

## ANNEX A

( Clause 11 )

### SAMPLING OF FORCEPS, DISSECTING AND LIGATURE, MIXTER'S PATTERN

#### A-1 LOT

In any consignment, all the instruments produced from the identical material under similar conditions and having the same surface finish shall constitute a lot.

**A-2** The number of instruments to be selected from each lot shall depend upon the size of the lot and shall be in accordance with col 1 and 2 of Table 1.

**A-2.1** These instruments shall be selected from the lot at random and in order to ensure

randomness of selection, procedures given in IS 4905 : 1968 may be followed.

**Table 1 Scale of Sampling**  
( Clauses A-2, A-3.1 and A-3.2 )

Lot Size	Sample Size	Sub-sample Size
(1)	(2)	(3)
Up to 15	2	1
16 to 50	3	1
51 to 150	5	2
151 and above	8	3



**A-3 NUMBER OF TESTS AND CRITERIA FOR CONFORMITY**

**A-3.1** All the instruments selected according to col 1 and 2 of Table 1 shall be examined for shape and dimensions, workmanship and surface condition (visual), and tested for mass. An instrument in the sample failing to meet any of these requirements shall be considered as defective. The lot shall be considered as conforming to these requirements if no defective is found in the sample.

**A-3.2** The lot having been found satisfactory according to **A-3.1** shall be further tested for other requirements. For this purpose, a sub-sample of size given in col 3 of Table 1 shall be taken. These instruments in the sub-sample may be selected from those already examined according to **A-3.1**. Each instrument in the sub-sample shall be subjected to hardness load closure, flexibility and corrosion resistance tests. The lot shall be declared as conforming to the requirements of the specification, if none of the instruments in the sub-sample fails in any of these tests.

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## Bureau of Indian Standards

harmonious development of the activities of standardization, marking and quality certification of goods and attending to connected matters in the country.

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